PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
David R. MILLER et al.	:	Confirmation No.: 4583
Application No. 10/695,441	:	Art Unit: 3736
Filed: October 29, 2003	:	Examiner: Robert Nasser
For: BLADDER-BASED CUFF FOR MEASURING PHYSIOLOGICAL PARAMETERS AND METHOD OF MEASURING PHYSIOLOGICAL PARAMETERS USING SAME	:	Atty Docket: P67936US0

DECLARATION UNDER 37 C.F.R. § 1.132 OF DAVID BELL

Mail Stop AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, DAVID A. BELL, declare that:

1. I am one of the inventors of the invention that is the subject of the present patent application.

2. My qualifications are as follows:

Education Degrees and Certifications

BS Political Science (Pre-law emphasis), Utah State University /Brigham Young University, 1975

MS Mechanical Engineering, Utah State University, 1977

PhD Engineering, (Computational Fluid Dynamics Dissertation), Utah State University, 1984

PE, Registered Profession Engineer, Mechanical and Fluids Engineering, Utah and Oregon, 1984-present

Experience

1975 – 1977	Graduate Research and Teaching Assistant, College of Engineering and School of Business MBA program, Utah State University, Logan, Utah
1977 – 1979	Project Engineer R&D Tektronix, Beaverton, Oregon; Peterson Associated Professional Engineers, Portland, Oregon
1979 – 1984	Faculty, Sr. Research Fellow, College of Engineering, Utah State University, Logan, Utah
1985- Present	Adjunct Professor, College of Engineering, University of Utah
1984 – '93	Sr. VP R&D, EFI Electronics Corporation, Salt Lake City, Utah
1993- Present	CTO, Executive VP R&D, HemaMetrics Corporation, Kaysville, Utah

3. I have read and understand the Office Action dated December 12, 2005 issued in connection with this application, and U.S. Patent No. 5,807,266 to Itonaga ("the Itonaga patent" or "Itonaga") cited in the Office Action.

4. The Itonaga patent states at column 4, lines 1-15):

> FIG. 2 shows a finger-type blood pressure monitor which is somewhat different in appearance from that shown in FIG. 1. This monitor has a protruding catch 4a on the end of cover 4 and a corresponding indentation 4b on the interior surface of chamber 3. When cover 4 is closed, catch 4a engages with indentation 4b to insure that the cover will be securely closed. A portion of finger cuff 2 is fixed to the interior of cover 4. When cover 4 is opened, cuff 2 is drawn out of chamber 3 and assumes a cylindrical form suitable for the insertion of a finger. When cover 4 is closed, it pushes cuff 2 down so that it folds in two as it returns to chamber 3. Cuff 2 has three photoelectric sensors 10 to detect the pulse. The light from a luminous element within the cuff is

emitted onto the finger, and the light reflected by the finger is detected by photodetector elements.

5. Itonaga also makes reference to using the detectors or sensors to detect a pulse throughout the application, for example, at column 2, lines 60-64; column 4, line 12; column 4, lines 59-65; and column 6, lines 24-32. Although Itonaga uses the words "pulse detectors or photoelectric pulse sensors," in my opinion these elements are ordinary photodiodes, not "pulse sensors," with "pulse" being used to refer to a defined amplitude and frequency.

6. The true purpose of Itonaga's detectors is described at column 2, lines 34-37 ("With the blood pressure monitor of this invention, the pulse may be detected and pressurization of the cuff begun as soon as the user inserts the finger in the cuff. The user does not need to push a button to start the measurement, so the monitor is easier to operate.") and at column 6, lines 5-10 ("If the cuff is to be pressurized automatically, it should be pressurized a fixed interval after the aforesaid pulse detectors (photoelectric sensors) 10 have detected that a finger has been inserted in the cuff."). In other words, the "light from a luminous element" described by Itonaga is used as a go, no-go, or more specifically, finger or no-finger, system switch (see column 6, lines 6-9). The luminous element and the photodetectors are not used by Itonaga in measuring blood pressure or any other physiological parameter. On the contrary, blood pressure values are established in the same way as in conventional blood pressure cuffs, as shown in steps 7 and 8 of the flow chart of Figure 12 and as described at column 7, lines 1-4 ("The cuff is pressurized (Step 7), the maximum and minimum blood pressure values are established (Step 8) and the results are displayed on display 7 (Step 9).").

7. If pulse detection and quantification were Itonaga's goal, he would have been much more specific about the luminous element and its location, because if the luminous element is located too far away, a weak pulse will not be detectable. Rather, the location of the luminous element is not described or illustrated, nor is its power source or its window to the finger.

8. The position of the luminous element is not specified in the drawings and is not exactly located in terms of a datum (relative to the sensors) because it does not have to be so specified or located when used for switch purposes. If it really were used for pulsatile measurements of some kind, its position would have to be exact relative to the detectors, and this location would be immovable in use, which would not meet the design criteria associated with Itonaga's flexible circuit as described at column 2, line 67 – column 3, line 3.

9. Another indication that pulse detection and quantification were not Itonaga's goal is that the frequency of the luminous element is not specified. The frequency does not have to be specified because in Itonaga's device, the light from the luminous element simply has to detectable when on—like a flashlight through a finger. Light from this element is reflected down the finger surface, across the blackened and shiny surface of the cuff to an "optical" opening occupied by a detector element. Three detectors are provided to ensure that at least one of them "sees" a change of state produced by light which was bounced along the finger to the clearer portions of the bladder fabric. Non-blackened portions of the cuff increase the "infrared transmission factor" of the cuff fabric adjacent to the detectors (see column 2, lines 60-69 and also column 6, lines 7-9).

10. Finally, if the luminous element and photodetectors were for measuring physiological parameters, the distance from the source would most likely be exactly specified in terms of a physical separation distance, or "mean free path of photons," or something along a path or line.

11. It is therefore my opinion that when Itonaga refers to sensing a pulse, he really means a change in the signal from some value to another (lighter to darker) light to shadow, etc., or more specifically, the detection of a human finger.

12. It is also my opinion that the luminous element must be on the outside, not inside of the cuff, in contrast to the emitters of the present invention as recited in claims 12 and 19, which are located in the enclosed internal volume between the bladder surfaces .

13. If Itonaga's luminous element is inside the bladder and the bladder cuff surface is as opaque as implied, the bladder must have a window to permit light emission into the finger. No window is specified. On the other hand, the window transparency associated with the sensors is over-specified. Further, no light source is part of the internal PCB that contains the photodiodes. If indeed the luminous element is inside the cuff, there is no apparent path for the light except directly to the photodiodes, which defeats the stated purpose of the windows. One can only assume that the luminous element interfaces with the finger outside the cuff.

14. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (under 18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

15. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Date: 10 March 2006

David A. Bell